

### REMARKS

Claims 26-71 were pending in the subject application. Applicants have herein amended claims 26-28, 31-33, 39-40, 43-44, 46, 52-58, 67 and 70, added claim 73 and canceled claims 29-30, 59-66 and 71-72 without prejudice to their right to pursue the subject matter of these claims in another application. Support for these amendments may be found inter alia in the specification as follows: page 1, line 30 and page 6, lines 21-30. Therefore, claims 26-28, 31-58, 67-70 and 73 will be pending upon entry of this amendment.

#### Rejection under 35 USC §112, Second Paragraph

The Office Action rejected claim 58, alleging that the specification does not define what is meant by small organic compound.

In response, applicants respectfully traverse, and submit that one skilled in the art would understand what is meant by small organic compound. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the application have amended the claim such it no longer recites "small." Claim 58 currently recites "organic compound" and thus can embrace an organic compound without any restraint on size, and this still embraces small organic compounds, a term readily understood by those skilled in the art. Applicants contend that this amendment and the accompanying remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

#### Rejection under 35 USC §102(b)

The Office Action rejected claims 26-56 and 58-71 as allegedly being anticipated by Tracy et al. In response, applicants respectfully traverse this ground of rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application, have herein amended the claims. Applicants point out that the claims recite "biopolymer." Examples of such biopolymers, as set forth in claim 53, include peptides, nucleic acids, oligonucleotides, carbohydrates, gangliosides, and glycans. In contrast, Tracy et al. do not teach or suggest using a biopolymer. In fact, Tracy provides examples of suitable polymers at column 3, lines 45-63, none of which are biopolymers. Instead, the

polymers suggested in Tracy et al. include poly-vinyls, polyurethanes and other types of plastics, and not a biopolymer as recited in applicants' claims. Accordingly, applicants contend that Tracy et al. do not anticipate the claimed invention. Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

#### Rejection under 35 USC §102(b)

The Office Action rejected claims 26-56 and 58-71 as allegedly being anticipated by Violanto et al. In response, applicants respectfully traverse this ground of rejection. Nevertheless, applicants without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application, have herein amended the claims. Violanto et al. teach "**water-insoluble** compounds." In fact, column 2, lines 61-65 of Violanto et al. in the "Summary of the Invention" states that the "invention involves a method of making uniformly sized particles of a solid, **water-insoluble** organic compound..." [emphasis added]. In contrast, applicants note that claim 26 of their application recites: "[a] sustained release formulation of a precipitate of an **aqueous soluble** biopolymer, wherein the formulation is prepared by a process comprising exposure of the biopolymer in **aqueous solution** to an organic solvent under conditions resulting in the precipitate." [emphasis added]. Accordingly, applicants' biopolymer is aqueous soluble, in contrast to the water-insoluble compound described in Violanto et al. Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

#### Obviousness-Type Double Patenting Rejection

The Office Action rejected claims 26-70 under the judicially created doctrine of obviousness-type double patenting over claims 45-80 of U.S. Serial No. 10/193,654. The Examiner seems to be arguing that one set of claims is a species of the other. In response, applicants respectfully traverse this ground of rejection. Applicants point out that the claims pending in the subject application recite "sustained-release formulations." The claims in the copending application recite a "method of preparing a sustained release formulation." Neither is a species of the other since one set of claims relates to the formulation, while the other set of claims relates to a method of preparing the formulation. Applicants submit that this rejection has

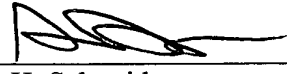
been rendered moot and therefore respectfully request reconsideration and withdrawal of the rejection.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. PBLI-P01-010 from which the undersigned is authorized to draw.

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Respectfully submitted,

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